

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (Previously Presented) A kit comprising firstly a lyophilized didemnin preparation and secondly, and separately contained, a reconstitution solution of mixed solvents,
wherein the lyophilized didemnin preparation comprises a didemnin compound and a water-soluble material;
wherein the reconstitution solution of mixed solvents comprises water for injection, an alkanol, and a nonionic surfactant, wherein the water for injection is present in an amount sufficient to allow solubilization of the water soluble material, and the alkanol is present in an amount sufficient to allow solubilization of the didemnin compound in the lyophilized didemnin preparation; and
wherein reconstitution of the lyophilized didemnin preparation with the reconstitution solution of mixed solvents provides a parenterally suitable preparation.
2. (Previously Presented) A kit according to claim 1, wherein the kit comprises an amount of the lyophilized didemnin preparation that is suitable for the treatment of a tumor in a patient.
3. (Previously Presented) A kit according to claim 1, wherein the didemnin compound is selected from didemnins, dehydrodidemnins, nordidemnins, didemnin congeners and didemnin analogs.
4. (Previously Presented) A kit according to claim 3, wherein the didemnin compound is aplidine.
5. (Cancelled)

6. (Cancelled)

7. (Previously Presented) A kit according to claim 1, wherein the nonionic surfactant is 10 to 25% v/v of the solution; the alkanol is 10 to 25% v/v of the solution; and the water for injection is 50 to 80% v/v of the solution.

8. (Previously Presented) A kit according to claim 1, which comprises a vial of lyophilized didemnin preparation comprising a water-soluble bulking agent, and a separate vial of a premix of non-ionic surfactant/ethanol/water for injection.

9. (Withdrawn) A method of preparing a pharmaceutical composition of a didemnin compound, which comprises freeze drying a didemnin/water-soluble additive/alkanol/water mix to provide a lyophilized first component, and separately providing an alkanol/water mix as reconstitution solution.

10. (Withdrawn) A method according to claim 9 wherein the alkanol in the mix is t-butanol.

11. (Withdrawn) A method according to claim 9 or 10 wherein the amount of alkanol in the alkanol/water mix is 25 to 60% v/v.

12. (Previously Presented) A reconstituted pharmaceutical composition comprising:
a didemnin compound;
a water soluble material;
a nonionic surfactant;
an alkanol; and
water for injection;

wherein the water for injection is present in an amount sufficient to allow solubilization of the water soluble material, and the alkanol is present in an amount sufficient to allow solubilization of the didemnin compound.

13. (Previously Presented) The pharmaceutical composition of claim 12, wherein the water soluble material is a water soluble bulking agent.

14. (Currently amended) The pharmaceutical composition of claim 13, wherein the water soluble ~~water soluble~~ bulking agent is mannitol.

15. (Previously Presented) The pharmaceutical composition of claim 12, wherein the didemnin compound is selected from the group consisting of a didemnin, a dehydrodidemnin, a nordidemnin, a didemnin congener or a didemnin analog.

16. (Previously Presented) The pharmaceutical composition of claim 15, where in the didemnin compound is aplidine.

17. (Cancelled)

18. (Previously Presented) The pharmaceutical composition of claim 12, wherein the nonionic surfactant is Cremophor EL.

19. (Previously Presented) The pharmaceutical composition of claim 12, wherein the alkanol is ethanol.

20-25. (Cancelled).

26. (Previously Presented) A kit according to claim 1, which comprises a vial of the lyophilized didemninn preparation and a separate vial of the reconstitution solution of mixed solvents.
27. (Previously Presented) A kit according to claim 1, wherein the didemninn compound is a dehydrodidemninn.
28. (Previously Presented) The pharmaceutical composition according to claim 12, wherein the didemninn compound is a dehydrodidemninn.
- 29-49. (Cancelled).
50. (Previously Presented) The pharmaceutical composition of claim 12, wherein the nonionic surfactant is 10 to 25% v/v of the nonionic surfactant/alkanol/water for injection mix; the alkanol is 10 to 25% v/v of the nonionic surfactant/alkanol/water for injection mix; and the water for injection is 50 to 80% v/v of the nonionic surfactant/alkanol/water for injection mix.
- 51.-52. (Cancelled)
53. (Previously Presented) The kit of claim 1, wherein the water soluble material is a water soluble bulking agent.
54. (Previously Presented) The kit of claim 53, wherein the water soluble water soluble bulking agent is mannitol.
55. (Previously Presented) The kit of claim 1, wherein the nonionic surfactant is Cremophor EL.

56. (Previously Presented) The kit of claim 1, wherein the alkanol is ethanol.
57. (Previously Presented) The kit of claim 7, wherein the alkanol is ethanol.
58. (Previously Presented) The reconstituted pharmaceutical composition of claim 50, wherein the alkanol is ethanol.
59. (Previously Presented) The kit of claim 1, wherein the alkanol is 10 to 25% v/v of the solution.
60. (Previously Presented) The kit of claim 59, wherein the alkanol is ethanol.
61. (Previously Presented) The reconstituted pharmaceutical composition of claim 12, wherein the alkanol is 10 to 25% v/v of the nonionic surfactant/alkanol/water for injection mix.
62. (Previously Presented) The reconstituted pharmaceutical composition of claim 61, wherein the alkanol is ethanol.
63. (Previously Presented) The kit of claim 1, wherein the lyophilized didemninn preparation is stable for at least 6 months when stored at +4°C in the dark.
64. (Previously Presented) The kit of claim 1, wherein the weight of the water-soluble material that is present in the lyophilized didemninn preparation is greater than the weight of the didemninn compound that is present in the lyophilized didemninn preparation.
65. (Previously Presented) The kit of claim 1, wherein the ratio of the weight of the water-soluble material that is present in the lyophilized didemninn preparation to the weight of the didemninn compound that is present in the lyophilized didemninn preparation is 25:1.

66. (Previously Presented) The reconstituted pharmaceutical composition of claim 12, wherein the reconstituted pharmaceutical composition is stable for at least 24 hours after dilution with normal saline up to 1:200.

67. (Previously Presented) The reconstituted pharmaceutical composition of claim 12, wherein the weight of the water-soluble material that is present in the reconstituted pharmaceutical composition is greater than the weight of the didemnin compound that is present in the reconstituted pharmaceutical composition.

68. (Previously Presented) The reconstituted pharmaceutical composition of claim 12, wherein the ratio of the weight of the water-soluble material that is present in the reconstituted pharmaceutical composition to the weight of the didemnin compound that is present in the reconstituted pharmaceutical composition is 25:1.

69. (Previously Presented) The kit of claim 1, wherein the reconstitution solution of mixed solvents comprises cremophor EL, ethanol, and water for injection in a ratio 15/15/70% (v/v/v).

70. (Previously Presented) The reconstituted pharmaceutical composition of claim 12, comprising: a didemnin compound, a water soluble material, cremophor EL, ethanol, and water for injection, wherein the cremophor EL, ethanol, and water for injection are in a ratio 15/15/70% (v/v/v).